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10/057,352	01/24/2002	Hien Vu Nguyen	PPC-823	2014
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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER REICHLE, KARIN M	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/057,352	Applicant(s) NGUYEN, HIEN VU	
	Examiner Karin M. Reichle	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-22-08 has been entered.

Election/Restrictions

2. Claims 3-13 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on 10-19-04 and 5-31-06.

Response to Amendment

3. The amendment to the claims has been entered but does not comply with 37 CFR 1.121. The parenthetical of claim 14 is incorrect, i.e. the claim is not an original claim but one that was previously presented. The next response, if any, should include the proper parenthetical for claim 14.

Specification

4. The disclosure is objected to because of the following informalities: 1) Is the structure of claims 3-10 and that on page 5, lines 1-5 and in the Examples 5-6 and abstract one and the same? If so, note the density of the former, i.e. 4 grams per cubic centimeter, as compared to the latter, i.e. 0.4 grams per cubic centimeter. Should the densities be the same? 2) At the very least, see also discussion in paragraphs 5-7 *infra*, as best understood the addition of glycerol monolaurate (GML) to the tampon or absorbent structure as now claimed in new claims 14-15 is inconsistent with the description of the remainder of the application. Specifically, the description at, e.g., page 10, lines 3-8 discloses that GML is added to the lyocell material, i.e. the tampon or the absorbent structure or the absorbent material, and such makes the lyocell more resistant to toxic shock syndrome, i.e. affects the characteristics of the lyocell (Note also the teachings of Huber '598 discussed in the prior art rejections *infra*) yet the manner in which such is claimed, i.e. "tampon comprising an absorbent structure which structure comprises absorbent material consisting essentially of hydrothermally treated lyocell fibers" (the terminology "consisting essentially of" limits the scope of the absorbent material to the specified fibers and that which does not materially affect the basic and novel characteristics of such absorbent material) as claimed in claim 1 and the "tampon" or "absorbent structure" which "comprises", i.e. at least includes, the "absorbent material" thereof, "further comprising glycerol monolaurate" as claimed in claims 14-15, respectively, infers it does not. A clear consistent description of the invention should be set forth throughout the application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1-2 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language “absorbent material consisting essentially of hydrothermally treated lyocell fibers” of claim 1 is unclear, see the discussion in the paragraphs 4 and 7, i.e. don’t know what “the basic and novel characteristics” of the absorbent material of the tampon are. The lack of clarity is further exacerbated by the use of the product by product terminology, i.e. “hydrothermally treated”. In regard to claims 14-15, these claims now require the tampon or absorbent structure further comprise glycerol monolaurate, i.e. GML. However, as set forth in claim 1 the absorbent material, i.e. at a minimum part of the tampon or structure, is set forth as “essentially consisting of” “hydrothermally treated” lyocell fibers. Therefore, the scope of the claims now unclear and/or inconsistent, i.e. does the absorbent material in claim 1 consist essentially of lyocell fibers? Comprise such fibers? Does the tampon of claim 14 or absorbent structure of claim 15 comprise such fibers and GML? Consist essentially of such fibers and GML? Note again the discussion in paragraphs 4 and 7. If the first and last, then the transitional language, i.e. “further comprising” in claims 14-15 is inconsistent. If the second and third, then the language “consisting essentially of” on lines 1-2 of claim 1 is inconsistent. See also the Claim Language Interpretation section and Response to Arguments section *infra*.

6. Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 14 and 15 now claim the tampon comprising an absorbent structure comprising absorbent material consisting essentially of hydrothermally treated lyocell fibers or the absorbent structure comprising absorbent material consisting essentially of hydrothermally treated lyocell fibers, respectively, further comprising glycerol monolaurate, i.e. GML. Applicant cites page 7, lines 13-22 and page 10, lines 3-8 as support for such claimed combinations. However, while such portions of the application in addition to others teach a tampon consisting of hydrothermally treated lyocell fibers, i.e. a tampon or absorbent structure or absorbent material consisting of hydrothermally treated lyocell, or such treated lyocell fibers in combination with other materials, e.g. GML, i.e. a tampon comprising an absorbent structure comprising absorbent material comprising such treated lyocell fibers and GML, i.e. the description, e.g., at page 7, teaches the GML as part of the hydrothermal treatment baths which baths are used to treat the lyocell fibers/absorbent material which fibers/material is used alone or in combination with other materials, this is not what is claimed, i.e. such portions do not set forth absorbent material of the tampon or absorbent structure consisting essentially of hydrothermally treated lyocell and such in a tampon or absorbent structure further comprising not only such material but also GML. See also discussion in paragraphs 4 and 5 supra and paragraph 7 infra. If Applicant maintains such claim language, the portion of the specification which provides support for the entire scope of the invention of each of the claims in a single embodiment should be set forth.

7. Claims 1-2 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written rejection. The language should focus on those factors reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in claim 1 the invention is an absorbent tampon comprising an absorbent structure comprising absorbent material consisting essentially of hydrothermally treated lyocell fibers.

Second, the terminology “consisting essentially of” is interpreted to limit the scope of the absorbent material to the specified fibers and that which does not materially affect the basic and novel characteristics of such absorbent material.

Third, new claims 14-15 now claim such tampon or absorbent structure, respectively, further comprising glycerol monolaurate, i.e. GML, which as disclosed at, e.g., page 10 is, e.g., a pharmaceutically active compound. See the discussion in paragraphs 4-6.

However and fourth, the instant application does not set forth what such “basic and novel characteristic(s)” to be so affected are considered to be, e.g. the application only discloses specific densities and absorbencies of a tampon of specific dimensions consisting of

hydrothermally treated lyocell fibers, not the “basic and novel characteristics” of an absorbent material as claimed.

Finally, while pages 6-10 of the instant application set forth the composition of the absorbent materials of absorbent structures, and thereby the tampons comprised thereof, as contemplated is not limited to only hydrothermally treated lyocell fibers but also combinations of such with other materials, e.g. both absorbent and non-absorbent, GML, i.e. a tampon comprising an absorbent structure comprising absorbent materials comprising such combinations, which other materials have the capability of affecting characteristics of an absorbent material, see, e.g. page 6, lines 19 et seq., it does not set forth the specifics of such combinations, i.e. what the exact compositions are, i.e. what the “basic and novel characteristics” of such combinations are and thereby, the absorbent materials composed thereof.

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. See also the Response to Arguments section *infra*.

Claim Language Interpretation

8. Claim 1 sets forth an absorbent tampon having a specific density and a specific Syngyna Absorbency. It is noted while the Test is described generally on page 11, lines 19-24, the specifics of such test have not been set forth nor are such specifics readily available to the Examiner nor has a copy of such FDA regulation been provided to the Examiner. See the prior art rejection *infra*. Claim 1 further sets forth that the tampon comprises an absorbent structure

comprising an absorbent material consisting essentially of hydrothermally treated lyocell fibers. It is noted the tampon is not required to consist essentially of such fibers nor has material which does essentially consist of the fibers nor the structure comprising such material been defined as requiring more than at least two fibers. Furthermore, the terminology "consisting essentially of" limits the scope of the absorbent material to the specified fibers and that which does not materially affect the basic and novel characteristics of such structure. However as set forth supra the instant application does not set forth what such "basic and novel characteristic(s)" of the absorbent material to be so affected are considered to be. Note additionally the lack of clarity/consistency discussed supra also now with regard to claims 1 and 14-15. Furthermore, claims 1-2 and 14-15 now require such fibers to be "hydrothermally treated", the claims are now product by process claims, see MPEP 2113, i.e. [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)." Therefore if a material of an end product including at least two lyocell fibers is absorbent it will be interpreted to read on the claim language.

Claim Rejections - 35 USC § 102/103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Woodings et al PCT '133.

See '133 at abstract, the last paragraph of page 1, page 2 line 27-page 3, line 22, page 4, lines 20-32, page 5, second full paragraph, and thereby GB '637 at page 1, lines 103-110, '133 at page 7, lines 1-19 and page 9, i.e. '133 teaches an end product which is an absorbent tampon comprising an absorbent structure comprising an absorbent materials "consisting essentially of" hydrothermally treated lyocell fibers, as best understood, see the Claim Language Interpretation section supra and Response to Arguments section infra. The tampon has a density of about 0.3 to about 0.5 grams per cubic centimeter, i.e. about 0.35, and an absorbency of at least about 4.4 g/g as claimed in claim 1 and at least about 5g/g as claimed in claim 2, see Tables 1 and 3, e.g. No. 5 of Table 1. Applicant claims the absorbency is determined by the "well known Syngyna Test", see page 10, lines 15-18 and page 11, last paragraph, i.e. the absorbency is termed the "Syngya Absorbency". It is the Examiner's first position that since the '133 reference teaches at page 5, lines 24-25, and thereby GB '637 at page 1, lines 103-108, assessing the tampon absorbency also by the known Syngyna test, i.e. the absorbency is termed the "Syngina Absorbency" in '133 instead, that Tables 1 and 3 as discussed supra teach the claimed absorbencies or teach such with at least "sufficient specificity", note also 2131.03. In any case, i.e. the Examiner's second position, since the tampon of '133 is made of an absorbent structure of absorbent material of hydrothermally treated lyocell fibers, as best understood, which fibers are processed as disclosed by the instant application, i.e. hydrothermally treated in a water bath of like temperature and time, and the tampon also has the claimed density, that there is sufficient factual evidence for one to conclude that such end product tampon would also inherently have or

necessarily and inevitably have the same absorbency when tested as disclosed by the instant application, if not already disclosed, i.e. have the same "Syngyna Absorbency". Note MPEP 2113 again especially the last paragraph thereof. Note also the Response to Arguments section *infra*.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodings '133 in view of Huber et al '598.

Claims 14 and 15 now claim the tampon comprising an absorbent structure comprising absorbent material consisting essentially of hydrothermally treated lyocell fibers or the absorbent structure comprising absorbent material consisting essentially of hydrothermally treated lyocell fibers, respectively, further comprising glycerol monolaurate, i.e. GML. While '133 does not teach such GML, it does teach the desire to use the solvent spun cellulose/lyocell taught thereby for the manufacture of tampons. Note also '133 at page 4, lines 16-19 of '133. It is also noted that it is not clear whether page 7, lines 6-22 and col. 10, lines 3-11 set forth that such GML is a conventional additive/agent or not. Therefore, see Huber et al '598 at col. 1, line 4-col. 2, line 50, i.e. use of GML for the amelioration of toxic shock syndrome in tampons manufactured from lyocell fibers. Therefore, to employ GML in combination with the tampon manufactured from lyocell fibers, i.e. the absorbent material, of '133 as taught by '598 would be obvious to one of ordinary skill in the art in view of the recognition that such would improve the safety of the

lyocell tampons manufactured, i.e. ameliorate toxic shock syndrome, and the desire to '133 to manufacture lyocell tampons as well as the desire of safety associated with any tampon manufactured.

Response to Arguments

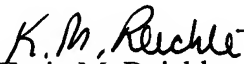
13. Applicant's remarks on pages 6-9 with regard to the matters of form and definiteness have been considered but are either deemed moot in that they have not been repeated or are deemed not persuasive for the reasons set forth supra, e.g. the remarks do not set forth the basic and novel characteristics of the absorbent material and/or where such are set forth in the description just that the claim language is limited to such and maybe be limited to such as per 2111.03 and summarily concludes the addition of GML does not affect characteristics of the absorbent structure, i.e. is "without affecting characteristics" the same as not "materially affecting the basic and novel characteristics" of the absorbent material and where are such "basic and novel" characteristics of the material and lack of "material affect" by GML thereon set forth pages 7-10 and '369? With regard to the arguments on the remaining pages of the remarks with respect to the prior art, such remarks have been considered but are deemed narrower than the prior art at, e.g., the abstract, and the claim language, i.e. "hydrothermally treated". "Hydrothermal" as defined by the dictionary is "of or relating to hot water" and '133 teaches treating with a "hot aqueous solution" and "aqueous" is defined by the dictionary as "pertaining to, similar to, containing or dissolved in water", i.e. treatment by a hot aqueous solution is "hydrothermal treatment".

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
January 31, 2008